

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11) Publication number:

0 247 717 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication of patent specification: **21.07.93** (51) Int. Cl.⁵: **A61N 1/32, A61F 7/00**

(21) Application number: **87303127.2**

(22) Date of filing: **09.04.87**

(54) **Corona discharge thermotherapy apparatus.**

(30) Priority: **28.04.86 US 856182**

(43) Date of publication of application:
02.12.87 Bulletin 87/49

(45) Publication of the grant of the patent:
21.07.93 Bulletin 93/29

(64) Designated Contracting States:
CH DE FR GB IT LI NL SE

(56) References cited:
DE-A- 3 049 484 DE-A- 3 340 104
DE-A- 3 347 600 FR-A- 2 336 145
GB-A- 2 026 322 US-A- 3 676 636
US-A- 4 572 194

J. KOWARSCHIK "Elektrotherapie", 2nd edition, 1923 Julius Springer, Berlin, pages 123-128

(73) Proprietor: **ADM Tronics Unlimited, Inc.**
153 Ludlow Avenue
Northvale New Jersey 07647(US)

(72) Inventor: **Di Mino, Alfonso**
15 Arcadia Road
Woodcliff Lake New Jersey(US)

(74) Representative: **Milhench, Howard Leslie et al**
R.G.C. Jenkins & Co. 26 Caxton Street
London SW1H 0RJ (GB)

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

Description

Field of the Invention:

This invention relates generally to thermotherapy, and in particular to a non-invasive technique for relieving pain and obtaining other salutary effects in which the skin surface of a patient overlying a problem region is subjected to a corona discharge beam derived by periodic bursts of radio frequency energy whose repetition rate is at a sonic frequency.

Status of Prior Art:

The term "problem region" as used herein refers to a set of muscles, an arthritic joint or any other site underlying the skin of a patient which is causing difficulty and which lends itself to treatment by thermotherapy.

The interior of the human body has a normal temperature level which is usually said to be 98.6°F. But actually, in the course of each 24-hour period, the body temperature rises above or falls somewhat below this nominal value. Body temperature is determined by the relationship existing between the amount of heat internally generated, which depends on basal metabolism and the amount of heat escaping from the body. Additional heat is produced as a result of muscular activity, this being dissipated by an increase in radiation, conduction or evaporation from the skin surface and by more rapid and deep breathing. If the heat produced by the body surpasses heat losses therefrom, this gives rise to fever.

Medical practitioners since ancient times have known that the application of heat to the body is useful in the relief of muscle soreness and various aches and pains, as well as in the treatment of certain pathological conditions. Thus the use of heat for the treatment of arthritis and other abnormalities is now commonplace. Hot water bottles and electrical heating pads are in widespread use, not merely to provide warmth, but also to afford a degree of relief or therapy for various conditions. In applying heat to the surface of the body, one may do so by convection, by direct contact with a warmed substance; that is, by conduction, or by radiating energy into the body.

As pointed out in chapter 10, "Therapeutic Heat" in the text Therapeutic Heat and Cold, edited by Justus F. Lehmann and published in 1982 by Williams and Wilkins, it is generally accepted that heat produces desirable therapeutic effects, for it increases the extensibility of collagen tissues, it decreases joint stiffness, and it affords pain relief. Moreover, heat relieves muscular spasms, it aids in the resolution of inflammatory infiltrates, edema

and exudates, and it enhances blood flow.

The exact physiological mechanisms by which applied heat creates soothing and analgesic effects are not known. However, regardless of how heat is generated, the result within the heated tissue is essentially the same, for heat produces a rise in the temperature of the tissue with a concomitant increase in metabolism. As a consequence, there is a relative increase in the accumulation of metabolic wastes such as carbon dioxide and acid metabolites. And because heat acts as a vasodilator, this dilation results in increased local circulation and leads to improved cellular nutrition and to an enhanced exchange of wastes. Further benefits are obtained because a greater number of phagocytes and antibodies are carried by the blood into the region being heated.

A technique in accordance with the invention makes use of converse heating which involves the transformation of some other form of energy into heat. The most commonly used sources of such energy are radio waves in the short wave and microwave bands of the electromagnetic wave spectrum, and ultrasonic energy. Shortwave diathermy uses radio waves in the 10 to 100 MHz frequency range, the human tissues being treated with high-frequency current, either by way of induction or conduction. In microwave diathermy, the frequency is usually about 2500 MHz. While shortwave diathermy tends to spread widely in the body tissues, microwaves are quasi-optical and can be focused and directed for the heating of small selective areas.

Ultrasonic therapy employs high-frequency sound waves, but this energy is selective in its heating properties. Because ultrasonic energy is reflective at interfaces in the body, in excessive dosages it may be destructive.

The present invention involves a therapeutic technique in which a corona discharge beam is created by applying to a discharge electrode bursts of radio-frequency energy whose repetition rate is at a sonic frequency. Hence, of background interest are the Di Mino patents US-A-3,676,633 and US-A-3,617,684, in which a corona discharge beam is applied to a resistor in a printed circuit so as to change the ohmic value thereof. These patents, however, have nothing to do with thermotherapy.

Also of background interest is the Hance et al. patent US-A-4,368,410, which discloses an ultrasound therapy technique in which the ultrasound energy is pulsed. In the Kuris et al. patent US-A-3,980,906, ultrasonic energy modulated at a sonic rate is applied to a vibrating toothbrush or razor. And in Indeck, US-A-4,343,301, non-invasive neurosurgery is performed using two ultrasonic beams to create a low frequency beat pattern.

Also in the field of ultrasonic therapy, we find the patents to Kofsky et al., US-A-4,177,819; Nemic, US-A-4,153,061; and Griffith, Jr., US-A-3,096,768.

GB-A-2,026,322 describes an apparatus for tissue treatment by electrotherapy wherein means are provided to overmodulate a radio-frequency carrier signal using a sonic frequency modulation signal whereby to periodically interrupt said carrier signal thereby providing bursts of radio-frequency energy in discrete periodically spaced relationship, and an electrode to which said bursts of radiofrequency energy are applied for effecting treatment of a tissue treatment area in operative relationship with the electrode. This apparatus is for stimulating bone growth and healing of soft tissue cells and comprises one or more contact electrodes for placing on the skin surface to apply an electric potential to the underlying tissue. The apparatus of GB-A-2,026,322 is not a thermotherapy apparatus.

US-A-4,572,194 discloses an electrotherapy apparatus in which a continuous corona discharge is produced by a rectified high voltage.

In accordance with the invention there is provided apparatus for tissue treatment by electrotherapy wherein means are provided to overmodulate a radio-frequency carrier signal using a sonic frequency modulation signal whereby to periodically interrupt said carrier signal thereby, providing bursts of radio-frequency energy in discrete periodically spaced relationship, and an electrode to which said bursts of radiofrequency energy are applied for effecting treatment of a tissue treatment area in operative relationship with the electrode, as known from GB-A-2,026,322 abovementioned, the apparatus of the invention being characterised in that said electrode is a non-contact corona discharge electrode adapted to create a corona discharge beam impinging on said tissue treatment area when the electrode is supplied with said bursts of radio-frequency energy and is spaced from said tissue treatment area.

Described hereinafter is an embodiment of the present invention comprising a thermotherapy apparatus for relieving pain and obtaining other beneficial effects by subjecting the skin of a patient in an area overlying a problem region to a corona discharge beam derived from a low radio-frequency power source, the corona discharge beam having no adverse effects on the patient. The term "low radio-frequency" as used herein refers to that band in the radio frequency spectrum which lies in the 100,000 to 1,000,000 Hz frequency range normally used for long distance communication.

This low radio-frequency band is largely reserved for radio telegraphy but has not heretofore been used in diathermy. The radio-frequency power for producing the corona discharge beam is

generated in periodic bursts whose repetition rate is at a sonic frequency. Use is made of a discharge electrode probe which can be manipulated to scan any skin area of a patient overlying a problem region. A corona discharge beam is projected from the tip of the electrode and impinges on the skin to be absorbed by the underlying tissue of the patient and converted into therapeutic heat. The corona discharge beam is derived from an energy generating unit in which a low radio-frequency carrier of relatively low power is overmodulated by a sonic frequency signal to create discrete spaced periodic bursts of radio-frequency energy whose repetition rate is at the sonic frequency and whose peak amplitude is such as to cause a corona discharge.

The above and further features of the invention are set forth with particularity in the appended claims and will be explained in the following detailed description of an embodiment of the invention which is to be read in conjunction with the accompanying drawings.

DESCRIPTION OF DRAWINGS

Fig. 1 illustrates the basic components of the system used in practising a thermotherapy technique in accordance with the invention;

Fig. 2 is a block diagram showing the various stages of the energy-generating units included in the system;

Fig. 3 illustrates the waveform of the power applied to the discharge electrode included in the system; and

Fig. 4 shows an alternative form of probe having multiple electrodes.

DESCRIPTION OF INVENTION

The Basic Technique:

Referring now to Fig. 1, a technique in accordance with the invention makes use of an energy-generating unit 10 which yields periodic bursts of radio-frequency energy whose repetition rate is at a sonic frequency. This energy is applied via a flexible wire 11 to a hand-held probe 12 having a pointed discharge electrode 12A from which is projected a corona discharge beam B. Beam B is directed toward and impinges on the skin surface 13 of a patient that overlies a problem region 14.

The tip of electrode 12A is placed within a few centimeters of the skin, the distance between the tip and the skin being such that the corona discharge beam impinges on the skin to be absorbed by the underlying tissue of the patient and converted into therapeutic heat. The zone of impingement, because of the corona discharge beam, is small, and in order to irradiate a relatively large

skin area, the beam is scanned over this area so that the entire problem region therebelow is subjected to treatment.

A corona discharge is a highly active glow region surrounding a discharge electrode. When the electrode is a pointed wire as in the present case, this glow region extends a short distance beyond this point. Assuming the wire is negatively charged, the free electrons in the air in the region of the intense electric field surrounding the wire gains energy in this field to produce positive ions and other electrons by collision. In turn, these new electrons are accelerated and produce further ionization. This cumulative process results in an electronic avalanche in which the positive ions are accelerated toward and bombard the charged wire. As a consequence of such ionic bombardment, secondary electrons are ejected from the wire surface which act to sustain the corona discharge.

When the voltage applied to the discharge electrode is elevated to a level exceeding the point at which a stable corona discharge is maintained, the air dielectric then completely breaks down to cause a spark discharge. In order to produce a corona discharge, the peak voltage on the discharge electrode must be relatively high but below the level resulting in a spark discharge.

The continuous application of a low radio-frequency energy of relatively low power will not result in a corona discharge. But because in the energy-generating unit 10, the continuous radio-frequency carrier is produced in bursts which shock excite a tank coil included in the system, the resultant energy surges have a peak amplitude sufficient to produce a sustained corona discharge beam.

The Energy Generating Unit:

Referring now to Fig. 2, the energy generating unit 10 includes a low radio-frequency generator 15 producing a carrier lying in the frequency range of 200,000 to 300,000 Hz. In practice, this generator is frequency controlled by a piezoelectric crystal oscillator operating at, say, 200 KHz, the carrier generator also being stabilized as to amplitude. A conventional low radio-frequency generator may be used for this purpose.

Also included in the unit is an audio-frequency generator 16 operating in the frequency range of 3000 to 5000 Hz to produce a sonic signal. This is amplified in amplifier 17 and applied to a coupler 18 which is so connected to radio-frequency generator 15 to effect amplitude modulation of the R-F carrier. Audio oscillator 16 is preferably a shielded, solid-state, transistorized generator which yields a steady monovalent signal with tolerances as minimal as present standards will allow. Amplifier 17 is

also transistorized.

In amplitude-modulation, the amplitude of the radio-frequency carrier is varied in accordance with the signal, the resultant modulated wave containing side bands that are the sum and difference of the carrier and signal frequencies. If the modulation index "M" is zero, no signal information is conveyed to the carrier. Where, however, $M = 1$ (100% modulation), then in the case of a sinusoidal carrier wave, the envelope of the carrier varies from zero to twice the value of its unmodulated amplitude. But if "M" exceeds unity, the carrier is then overmodulated, as a consequence of which the carrier is periodically interrupted at a repetition rate in accordance with the audio-frequency signal.

In the present invention, as shown in Fig. 3, the radio-frequency carrier C is overmodulated by the sonic frequency signal, this resulting in periodic bursts P_1, P_2, P_3 , etc. of radio-frequency energy whose repetition rate is at the sonic frequency. These bursts of energy from R-F generator 15 are applied through an output amplifier 19 to a tank coil 20. Coil 20 is inductively coupled to an output coil connected by flexible lead 11 to probe 12.

Because tank coil 20 is shock excited by the bursts P_1, P_2 etc. of the radio-frequency energy, the resultant damped wave surges in coil 20 have a high peak amplitude, and this causes the desired corona discharge to produce a pencil beam which is both visible and audible. The reason it is visible is that the corona beam produces a blue glow, and the reason it is audible is that the bursts of energy are at a sonic rate and can therefore be heard. In practice, the power output of the system may be in the order of 5 to 15 watts. This level is far below any level that would result in burning or injury to a patient.

We have found that the resultant heat energy induced in a painful region of the human body is capable in a matter of 20 seconds of relieving this pain. We have also found that continued exposure of the problem region for a period of 30 to 40/seconds to the corona charge beam, in the case of inflammation due to a rheumatoid arthritis condition, will minimize the swelling, and that a marked reduction in swelling will be experienced about 24 hours after such exposure.

Claims

1. Apparatus (10,11,12) for tissue treatment by electrotherapy wherein means are provided to overmodulate a radio-frequency carrier signal using a sonic frequency modulation signal whereby to periodically interrupt said carrier signal thereby providing bursts (P_1, P_2 , etc.) of radio-frequency energy in discrete periodically spaced relationship, and an electrode (12A) to

which said bursts of radiofrequency energy are applied for effecting treatment of a tissue treatment area in operative relationship with the electrode, characterised in that said electrode is a non-contact corona discharge electrode adapted to create a corona discharge beam (B) impinging on said tissue treatment area when the electrode is supplied with said bursts (P₁, P₂, etc.) of radio-frequency energy and is spaced from said tissue treatment area.

2. Apparatus as claimed in claim 1 further provided with a radio-frequency carrier signal generator (15), a sonic-frequency oscillator (16) and a tank circuit (20) for storing said bursts of radio-frequency energy, wherein said discharge electrode (12A) is coupled to said tank circuit (20) and is movable by a user to a position adjacent said tissue treatment area (13,14) to direct the corona discharge beam (B) theretowards.
3. Apparatus as claimed in claim 1 or 2, wherein said radio-frequency carrier has a frequency in the low-frequency radio range.
4. Apparatus as claimed in claim 3, wherein said radio-frequency carrier signal has a frequency of about 200,000 Hz.
5. Apparatus as claimed in any of claims 1 to 4, wherein said sonic frequency lies in a range of about 3000 to 5000 Hz.
6. Apparatus as claimed in any of claims 1 to 5, wherein said radio-frequency signal has a power output of about 10 watts.
7. Apparatus as claimed in any of claims 1 to 6, wherein said electrode is constituted by a single pointed wire.
8. Apparatus as claimed in any of claims 1 to 6, wherein said electrode is constituted by a cluster of pointed wires to create multiple corona discharge beams.

Patentansprüche

1. Vorrichtung (10, 11, 12) zur Gewebebehandlung mittels Elektrophysiotherapie, worin Einrichtungen zur Übermodulation eines Radiofrequenz-Trägersignals mittels eines Schallfrequenz-Modulationssignals, um das Trägersignal periodisch zu unterbrechen, wodurch diskrete, periodisch von einander getrennte Signalbündel (P₁, P₂, etc.) mit Radiofrequenz-Energie erzeugt werden, und eine Elektrode (12A) vorge-

sehen sind, an die die Signalbündel mit Radiofrequenz-Energie zur Behandlung eines zu behandelnden Gewebebereichs durch Einsatz der Elektrode angelegt werden, dadurch gekennzeichnet, daß die Elektrode eine Nicht-Kontakt-Glimmentladungselektrode ist, die einen auf dem zu behandelnden Gewebebereich auftreffenden Glimmentladungsstrahl (B) erzeugt, wenn die Elektrode mit Signalbündel (P₁, P₂, etc.) mit Radiofrequenz-Energie versorgt wird und gegenüber dem zu behandelnden Gewebegebiet beabstandet ist.

2. Vorrichtung gemäß Anspruch 1, worin weiter ein Radiofrequenz-Trägersignalgenerator (15) ein Schallfrequenz-Oszillator (16) und eine Speicherschaltung (20) zum Speichern der Signalbündel mit Radiofrequenz-Energie vorgesehen sind, wobei die Glimmentladungselektrode (12A) mit der Speicherschaltung (20) verbunden und vom Anwender in eine zum zu behandelnden Gewebeabschnitt (13, 14) benachbarte Stellung bewegbar ist, um den Glimmentladungsstrahl (B) darauf zu lenken.
3. Vorrichtung gemäß Anspruch 1 oder 2, worin das Radiofrequenz-Trägersignal eine Frequenz im Niederfrequenz-Radiobereich besitzt.
4. Vorrichtung gemäß Anspruch 3, worin das Radiofrequenz-Trägersignal eine Frequenz von ca. 200,000 Hz besitzt.
5. Vorrichtung gemäß einem der Ansprüche 1 bis 4, worin die Schallfrequenz im Bereich von ca. 3000-5000 Hz liegt.
6. Vorrichtung gemäß einem der Ansprüche 1 bis 5, worin das Radiofrequenz-Signal eine Ausgangsleistung von ca. 10 Watt besitzt.
7. Vorrichtung nach einem der Ansprüche 1 bis 6, worin die Elektrode aus einem einzelnen spitzzulaufenden Draht besteht.
8. Vorrichtung gemäß einem der Ansprüche 1 bis 6, worin die Elektrode aus einer Gruppe von spitzzulaufenden Drähten zur Erzeugung von Multi-Glimmentladungsstrahlen besteht.

Revendications

1. Appareil (10, 11, 12) de traitement d'un tissu par électrothérapie dans lequel sont prévus un moyen apte à surmoduler un signal porteur de radiofréquence en utilisant un signal de modulation de fréquence sonore, afin d'interrompre ainsi périodiquement ledit signal porteur en

formant ainsi des paquets (P_1 , P_2 , etc.) d'énergie de radiofréquence dans une relation discrète espacée périodiquement, et une électrode (12A) à laquelle sont appliqués lesdits paquets d'énergie en radiofréquence afin d'effectuer un traitement d'une zone de traitement de tissu en relation fonctionnelle avec l'électrode, caractérisé en ce que ladite électrode est une électrode de décharge corona sans contact apte à créer un faisceau de décharge corona (B) frappant ladite zone de traitement du tissu lorsque l'électrode est alimentée par lesdits paquets (P_1 , P_2 , etc.) d'énergie de radiofréquence et est espacée de ladite zone de traitement du tissu.

5

10

15

2. Appareil selon la revendication 1 comprenant en outre un générateur (15) de signaux porteurs de radiofréquence, un oscillateur à fréquence sonique (16) et un circuit d'accumulation (20) pour accumuler lesdits paquets d'énergie de radiofréquence, dans lequel ladite électrode de décharge (12A) est couplée audit circuit d'accumulation (20) et peut être déplacée par un utilisateur vers une position adjacente à ladite zone de traitement du tissu (13, 14) afin d'orienter vers celle-ci le faisceau de décharge corona (B).
3. Appareil selon la revendication 1 ou 2, dans lequel la fréquence dudit porteur de radiofréquence est dans la plage de radio de basse fréquence.
4. Appareil selon la revendication 3, dans lequel la fréquence dudit signal porteur de radiofréquence est d'environ 200.000 Hz.
5. Appareil selon l'une quelconque des revendications 1 à 4, dans lequel ladite fréquence sonique est située dans une plage d'environ 3000 à 5000 Hz.
6. Appareil selon l'une quelconque des revendications 1 à 5, dans lequel la sortie de puissance dudit signal radiofréquence est d'environ 10 watts.
7. Appareil selon l'une quelconque des revendications 1 à 6, dans lequel ladite électrode est constituée par un fil pointu unique.
8. Appareil selon l'une quelconque des revendications 1 à 6, dans lequel ladite électrode est constituée par un ensemble de fils pointus afin de créer de multiples faisceaux de décharge corona.

20

25

30

35

40

45

50

55

